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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/587,067 | 11/05/2008 | Paul Vermeij | 1-2004.001 US | 1685 |

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Intervet/Schering-Plough Animal Health
Patent Dept. K-6-1, 1990
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

| EXAMINER | |
|---|---|
| SWARTZ, RODNEY P | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 10/13/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/587,067 | VERMEIJ, PAUL | |
| | Examiner | Art Unit | |
| | Rodney P. Swartz, Ph.D. | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20July2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *10-13,25-29 and 31-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13,25-29 and 31-39* is/are rejected.

7)☒ Claim(s) *26,27 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20July2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicants' Preliminary Amendment, received 20 July 2006, is acknowledged. Claims 1-9, 14-24 and 30 have been cancelled. Claims 10, 11, 12, 13, 25, 26, 27, 28, 29, 31 and 32 have been amended. New claims 33-39 have been added.

2. Claims 10-13, 25-29 and 31-39 are pending and under consideration.

## Specification

3. The disclosure is objected to because of the following informalities:

Page 1, line 1, the priority must be amended to indicate how the application is "related to", e.g., the application is the national stage of PCT.....

Page 1, line 19, define "FCR"; line 24, "have been name" should be "have been named"; line 28, "emoe" should be "emu".

Page 2, line 9, "has not lead" should be "has not led".

Page 4, line 31, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 5, lines 8 and 24, "hybridise" should be "hybridize"; line 10, "hybridises" should be "hybridizes".

Page 11, line 8, "encoding a any" should be "encoding any".

Page 12, line 9, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 16, line 10 "to man skilled" should be "to one skilled".

Page 17, line 28, "immunisation" should be "immunization".

Page 20, lines 7 and 9, "stabilisers" should be "stabilizers"; line 14, "adjuvating" should be "adjuvanting"; line 15, "stabilising" should be "stabilizing".

Page 22, line 10, "characterised" should be "characterized"; line 17, "immunising" should be "immunizing"; lines 24-25, contain an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 24, line 5, "from pigs died" should be "from pigs which died".

Page 28, line 9, "recognised" should be "recognized".

Page 29, line 9, "recognised" should be "recognized".

Page 30, line 8, "recognised" should be "recognized".

Page 31, line 6, "recognised" should be "recognized".

Page 33, line 5, what is meant by "After incubation conform the protocol"?; line 19, "recognising" should be "recognizing".

Page 34, line 13 what is meant by "After incubation conform the protocol"?

Page 35, line 3, "recognises" should be "recognizes"; line 26, what is meant by "After incubation conform the protocol"?

Page 36, line 8, what is meant by "was seen in with coupes cut from the ilia"?; line 14 "recognises" should be "recognizes".

Page 37, line 15, what is meant by "After incubation conform the protocol"?; line 26, "recognised" should be "recognized".

Page 38, line 9 "Experimental" should be "experimental".

Page 41, line 13, "Table 1" should be "Table 6" for consistency with the rest of the specification which has Table 1-5 already present.

Page 42, line 1, "Table 1" should be "Table 6" for consistency with the rest of the specification which has Table 1-5 already present.

Appropriate correction is required.

**Sequence Requirements**

M.P.E.P.§2422.03, paragraph 9 recites:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the"Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

Page 27, lines 15 and 16 contain sequences without the required SEQ ID numbers.

Page 28, lines 15 and 16 contain sequences without the required SEQ ID numbers.

Page 29, lines 15 and 16 contain sequences without the required SEQ ID numbers.

Page 30, lines 13 and 14 contain sequences without the required SEQ ID numbers.

Page 31, Table 1 contains sequences without the required SEQ ID numbers.

Pages 32-33, Table 2 contains sequences without the required SEQ ID numbers.

Page 34, Table 3 contains sequences without the required SEQ ID numbers.

Page 35, Table 4 contains sequences without the required SEQ ID numbers.

Page 37, Table 5 contains sequences without the required SEQ ID numbers.

## Claim Objections

4. Claim 26 is objected to because it improperly depends from claim 25. Claim 25 does not list "adjuvant" as a component. It is recommended that claim 26 recite "futher comprising an adjuvant". Appropriate correction is required.

5. Claim 27 is objected to because it improperly depends from claim 25. Claim 25 does not list "an additional antigen" as a component. It is recommended that claim 27 recite "futher comprising an additional antigen". Appropriate correction is required.

6. Claim 33 is objected to because of the following informality: line 1, "*Lawonia*" should be "*Lawsonia*". Appropriate correction is required.

## Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim is drawn to a host cell comprising a nucleic acid according to claim 33. The nucleic acids of claim 33 are isolated from *L. intracellularis*. Thus, the construct of claim 13 reads on a naturally occurring *L. intracellularis*.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10-13, 25-28, 33 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is drawn to an isolated nucleic acid that hybridizes "under stringent conditions" with a sequence selected from a group of sequences. The claim is vague and indefinite because the phrase "stringent hybridization conditions" is vague and indefinite because hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration, and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require a knowledge of these specific parameters. The claim does not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth in the claim the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure.

Claims 10-13, 25-28 and 36 depend from claim 33, but do not clarify the issue.

9. Claims 29, 31, 32, 34, 35 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is drawn to an isolated *L. intracellularis* protein or immunogenic fragment thereof, "having the same immunological characteristics" as an amino acid sequence selected from a group of listed sequences.

It is unclear how an immunogenic fragment can have all of the same immunological characteristics of a complete protein.

In addition, the specification does not define the metes and bounds of "having the same immunological characteristics". Thus, it is unclear what proteins/fragments are encompassed within the scope of the claim.

Claims 29, 31, 32, 35 and 37-39 depend from claim 34, but do not clarify the issues.

10. Claims 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites that a vaccine comprises an additional antigen "derived from" a virus or microorganism or genetic information.

The specification does not define the metes and bounds of the phrase "derived from", thus it is unclear what form of antigen is being claimed and what may or may not be included within the scope of the phrase. It is suggested that "an additional antigen isolated from" or "an additional antigen purified from" be used in place of "derived from".

Claim 28 depends from claim 27, but does not clarify the issue.

11. Claims 25-29, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for subunit vaccines comprising the *L. intracelluris* 75 kD, 44 kD, 26/31 kD and 27 kD proteins effective against *in vivo L. intracelluris* infections in pigs, does not reasonably provide enablement for subunit vaccines of only one subunit, or of subunits 27 kD, 62 kD, 57 kD, 74 kD, 43 kD or 101 kD. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention is drawn to a vaccine comprising only 1 DNA or protein of a selected group of purified *L. intracullaris* proteins.

The state of the prior art as evidenced by the instant specification indicates that at the time of filing of the instant application, *L. intracellularis* was not cultivated in cell-free media nor were the nine listed proteins identified.

Thus, there was a lack of predictability or lack thereof in the art that subunit vaccines would be successful against infections with *L. intracellularis*.

The amount of direction or guidance present is insufficient for the scope of the instant claims. While the proteins and their encoding DNA sequences were identified, the only working example example of a vaccine utilizes 4 multiple proteins (75 kD, 44 kD, 26/31 kD and 27 kD) in a combination composition for treating *L. intracellularis*. There are no examples of any vaccines utilizing less than these four proteins and no vaccines using the other claimed proteins (27 kD, 62 kD, 57 kD, 74 kD, 43 kD or 101 kD).

Therefor, the quantity of experimentation necessary to determine if any single subunit composition would function as an effective vaccine, or that vaccines comprising any one or

more of 27 kD, 62 kD, 57 kD, 74 kD, 43 kD or 101 kD proteins, constitutes merely an invitation for experimentation without a reasonable expectation of success.

**Conclusion**

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Larry Helms, at (571)272-0832.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

October 6, 2010